JUL 2 4 2012

Section 5. 510(k) Summary K121912

Submitter:	Masimo Corporation 40 Parker Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Contact:	David Collette Sr. Manager, Regulatory Affairs
Date Summary Prepared:	June 29, 2012
Trade Name:	Masimo E1 Ear Sensor
Regulation Name:	Pulse Oximeter
Classification Regulation:	21 CFR 870.2700 Class II
Product Code:	DQA
Existing Device:	K101031 – Masimo Disposable Oximetry Ear Sensors

Device Description

The Masimo E1 Ear Sensor is a single patient use device that is designed to be used with instruments that include or are compatible with the Masimo SET and Masimo Rainbow SET technologies.

The subject device is a modification of the existing device that provides improved oxygen saturation measurement accuracy.

Indications for Use

The Masimo E1 Ear Sensor is indicated for single patient use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for use with adult and pediatric patients, (weighing > 30kg), who are well or poorly perfused, in hospitals, hospital-type facilities, mobile, and home environments.

Specifications

The modified E1 Ear Sensor in this submission has been shown in verification and clinical validation studies to provide an improvement in the oxygen saturation accuracy specification from ± 3.5% to ± 2.5% (A_{RMS}) under no motion and both well- and poorly-perfused conditions.

E1 Ear Sensor Accuracy Specifications (A_{RMS})

Accuracy (A_{RMS})/ Conditions	Existing Device – K101031	Subject Device
No motion/ Well-perfused	SpO_2: ± 3.5% Pulse Rate: 3 beats/minute	SpO_2: ± 2.5% Pulse Rate: 3 beats/minute
No motion/ poorly-perfused	SpO_2: ± 3.5% Pulse Rate: 3 beats/minute	SpO_2: ± 2.5% Pulse Rate: 3 beats/minute

Summary of Testing

The following testing of the Masimo E1 Ear Sensor was performed in accordance with the requirements of the design control regulations and established quality assurance processes to demonstrate substantial equivalence of the modified device to the cleared device:

- Design Review Process
- Risk Analysis per ISO 14971
- Biocompatibility per ISO 10993
- Electromagnetic Compatibility per IEC 60601-1-2
- Electrical Safety Testing per IEC 60601-1
- Environmental Testing
- Component Testing
- Clinical Performance Testing

Conclusion

The information in this 510(k) submission demonstrates that the subject Masimo E1 Ear Sensor is substantially equivalent to the existing device with respect to safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 24 2012

Mr. David Collette
Senior Manager, Regulatory Affairs
Masimo Corporation
40 Parker
Irvine, California 92618

Re: K121912
Trade/Device Name: Masimo E1 Ear Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: June 29, 2012
Received: July 2, 2012

Dear Mr. Collette:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4. Indications for Use

Indications for Use

510(k) Number: K121912

Device Name: Masimo E1 Ear Sensor

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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